



Instructions for Use



SkinVision Version 6.0



SkinVision B.V.
Kraanspoor 28
1033 SE Amsterdam
info@skinvision.com



This product complies with the relevant requirements of the EU Directive 93/42/EEC

INTENDED USE

The SkinVision service is a software only mobile medical application for over the counter (OTC) use. The SkinVision service is intended to provide an immediate risk indication for the most common types of skin cancer of a specific spot on the skin, based on a photo taken with your mobile device. Based on the assessment, the SkinVision service provides a recommendation whether to visit a healthcare professional for further review. The SkinVision service creates skin health awareness and allows the user to monitor spots on the skin over time and provides guidance in discussions with healthcare professionals.

The SkinVision service is not intended to replace traditional methods of the evaluation of skin cancer risk level, is not a diagnosis, and is not a substitute for visits to a healthcare professional. The SkinVision service is not intended for use on children.

USING SKINVISION

1. SkinVision download and account creation

To get started:

- Download the SkinVision App from the App Store or Google Play Store on your compatible iOS or Android phone (www.skinvision.com/compatibility).
- Open the SkinVision app and follow the instructions to create an account.
- Take a photo of your skin spot using the app to make your first Smart Check.

2. Please note before you start

Do not use the app to take a photo of a skin spot that:

1. Is close in color with the surrounding skin, for example a skin spot on (very) dark skin (type V and VI per the Fitzpatrick scale) or on sunburnt skin,
2. has been previously damaged,
3. is surrounded by non-intact skin (e.g. open sores, ulcers, bleeding, scabs),
4. is under the nail(s),
5. is close to a (visible) area with scar(s),
6. contains foreign matter (e.g. marker, tattoo, sunscreen, skin cream, powder, etc.),
7. is covered by a significant amount of hair,
8. is on mucosal surfaces (e.g. lips, genitals),
9. is on or near a skinfold or,
10. is not on human skin.



SkinVision is not a diagnostic tool and does not replace a visit to a doctor. If you feel concerned about a spot that meets any of the above criteria, or you see the skin spot is infected, changing, bleeding or hurting, please consult your local healthcare professional.

3. Performing a Smart Check

- Find an evenly lit place where you can make a Smart Check. Avoid direct light sources that may cause shadows on or around your skin spot.
- Open the SkinVision app and click on the camera icon to open the Smart Camera.
- Aim the Smart Camera at the spot on the skin you want to assess and wait for the camera to focus.
- To help focus the camera, move your phone between 4-8 inches (10-20 cm) from the skin spot until the rings on the camera screen turn blue. Take enough time, most people are able to make a photo after some training.
- Once your Smart Photo has been taken, review the photo and confirm that this is indeed a clear and focused image of the skin spot you want to have assessed.
- Indicate whether any symptoms are present regarding the spot on the skin (no symptoms, bleeding, changing or infected). Multiple choices are allowed.
- Create a folder with the location of the skin spot to store the Smart Check in.
- Wait while the SkinVision service processes your photo.
- You will receive your risk indication of the assessed photo, an explanation of the result and a recommendation in terms of monitoring the skin spot and following up with your local healthcare professional.

4. Monitoring over time

- When finishing your Smart Check, you can set a reminder to check the skin spot in the future. At the chosen time, you will receive a push, text message or email. Dermatologists recommend that you check your skin every three months.
- You can adjust the frequency and type of reminders in the Settings menu in the app.
- Smart Checks that were made previously can be found on the profile screen within the folder you created. Make sure to store photos of

the same skin spot in the same folder. Photos that are not stored in a specific folder can be found in the “All pictures” folder.

5. Personal risk profile for skin cancer

- Select “Risk Profile” or “Skin Type” from the profile screen and take the quiz to receive information on your personal risk for skin cancer based on your physique, lifestyle and medical history.
- For information on the strength of the ultraviolet (UV) light in on your location, select “UV index” from the profile screen.

PROBLEM SOLVING

If you encounter any problems during the use of SkinVision, follow the instructions in the troubleshooting guide below or contact us at info@skinvision.com.

<p>Problem</p> <p>The Smart Camera does not detect my skin spot.</p>	<p>Solution</p> <ol style="list-style-type: none"> 1. Make sure that the view of the camera on the skin spot is not obstructed. 2. Center the camera on the skin spot so that the dot in the center of the camera interface turns green. 3. Make sure that there is enough lighting at your location so that your skin (spot) is lit evenly.
<p>Problem</p> <p>The Smart Camera does not focus on my skin spot.</p>	<p>Solution</p> <ol style="list-style-type: none"> 1. Vary the distance of the camera to the skin spot to between 4-8 inches (10-20cm) and allow the camera to focus.

	2. Tap on the camera screen on the location of the skin spot to refocus the camera.
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WARNINGS

General

1. Do not install or use the SkinVision app on a device with non-original iOS or Android ('jailbroken' or 'rooted') software.
2. Before using the SkinVision app, check that the camera lens is clean and not obstructed by anything. Wipe the lens carefully with a soft cloth if it is dirty.
3. Do not cover the flashlight source or the camera in any way while the photos are being captured.
4. Do not upload or transmit content of any type that may infringe or violate the rights of any party.
5. Do not disable, modify, "hack" or otherwise interfere with the proper functioning of this software.
6. The SkinVision service is not intended for use on children.

ADDITIONAL INFORMATION

For more detailed information, troubleshooting or technical information, please visit <https://www.skinvision.com/faq>

DISCLAIMER

Electronic communication is not appropriate for all health issues, particularly those of an urgent nature, and **SkinVision B.V.** makes no guarantee of any particular response time to any inquiries you may make, accordingly. If you are experiencing a medical emergency, you should not rely on this guide for assistance, but should instead seek appropriate emergency medical assistance.

SYMBOLS



Instructions for use



Manufacturer



CE Certified



Warning